



Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing.

FOR FURTHER INFORMATION CONTACT: Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Stabilized Influenza Hemagglutinin Stem Region Trimers and Uses Thereof

Description of Technology:

An effective universal influenza vaccine would eliminate the uncertain and costly process of seasonal influenza vaccine development each year. Researchers at the National Institute of Allergy and Infectious Diseases (NIAID) are developing immunogens which elicit neutralizing antibodies to the highly conserved stem region of the influenza viral protein hemagglutinin. By targeting this highly conserved region, which is nearly identical in various strains of influenza virus, these immunogens could train the immune system to defend against a wide variety of influenza strains including pandemic strains derived from animal reservoirs.

This vaccine candidate employs a protein nanoparticle platform to display portions of the highly conserved stem region of the group 1 hemagglutinin (HA) viral surface protein in its native, trimeric conformation. Animal studies have shown that the HA stem region trimers displayed on a nanoparticle are more immunogenic compared to HA stem region trimers alone. Immunization of mice and ferrets with an H1N1 nanoparticle HA stem immunogen conferred protection from a lethal dose of H5N1 virus.

NIAID is continuing development of these vaccine candidates through animal studies and moving toward clinical evaluation.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Universal influenza vaccine

Competitive Advantages:

- Nucleic acid or recombinant protein-based vaccine
- Increased ease of production relative to current seasonal influenza vaccines

Development Stage:

- Preclinical, animal data available

Inventors: John R. Mascola, Jeffrey C. Boyington, Hadi M. Yassine, Peter D. Kwong, Barney S. Graham, Masaru Kanekiyo (all from NIAID).

Publications: Yassine, H.M., et al. (2015) Hemagglutinin-stem nanoparticles generate heterosubtypic influenza protection. *Nature Medicine* **21**: 1065-1070. [PMID: 26301691]

Intellectual Property: HHS Reference Number E-066-2014 includes U.S. Patent Application No. 15/13,265 filed November 22, 2016 (Pending); Canada Patent Application No. 2,950,085 filed May 27, 2015 (Pending); China Patent Application No. 201580041202.3 filed January 24, 2017 (Pending); Europe Patent Application No. 15727824.3 filed December 23, 2016 (Pending); India Patent Application No. 201617042607 filed December 14, 2016 (Pending).

Related Intellectual Property: HHS Reference Number E-293-2011

Licensing Contact: Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize influenza monoclonal antibody technologies. For collaboration opportunities, please contact Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

Dated: April 5, 2018.

Suzanne M. Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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